

REMARKS

Claims 1-14, 16-19, 21-25, 27, 28, 30-32, 34-37 and 39-41 remain pending in the present application. Claims 1-13, 17-19 and 35-37 stand withdrawn subject to the restriction/election of species requirement previously issued by the Examiner. Claims 15, 20, 26, 29, 33 and 38 are canceled.

The amendment to claims 14 and 28 to incorporate specific "analogs" of Tranilast is submitted in response to the formal rejection made by the Examiner in the last Office Action, and finds basis in the specification at page 7, line 19, bridging to page 8, line 23. The amendment to claims 14 and 28 to limit the claims to barriers is commensurate with Applicants' election of species, i.e. "barriers" in their response of 2 October 2007, and finds basis at page 13, lines 7-22 and page 17, line 22, through page 19, line 8 of the specification. Additional amendments are merely directed at incorporating the subject matter of various dependent claims into earlier claims, corrections of typographical errors, and corrections of dependencies. No new matter is submitted.

Rejection under 35 U.S.C. §112

Claims 14-19, 21-25, 27-37 and 39-41 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to define the word "analog"; for incorrect dependencies; and for lack of antecedent basis for the phrase "said absorbable barrier". Applicants believe the rejections to have been mooted in view of their amendment herein. Withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. §102(b)

Claims 14-16, 21, 24, 25, 28 and 31-33 stand rejected under 35 U.S.C. §102(b) as anticipated by Isaji et al. (U.S. Patent No. 6,407,139) or Mori et al. (U.S. Patent No. 6,239,177) or Yamamoto et al. (U.S. Patent No. 5,356,620). Applicants traverse these bases for rejection and respectfully request reconsideration and withdrawal thereof.

As discussed above, the instant claims have been limited to barriers containing Tranilast or its analogs, commensurate with the election of species. None of the cited references discloses barriers selected from the group consisting of film, foam, fibers, and filaments containing Tranilast or its analogs.

Isaji et al. disclose compositions containing Tranilast in the form of powders, granules, fine granules, dry syrups, tablets, capsules, ointments, injections and eye drops (col. 4, lines 30-33). Isaji et al. fail to disclose barriers selected from the group consisting of film, foam, fibers, and filaments.

Mori et al. disclose external preparations containing Tranilast for high percutaneous absorption (abstract), such as patches for external application (col. 5, lines 13-19). Mori et al. fail to disclose barriers selected from the group consisting of film, foam, fibers, and filaments.

Yamamoto et al. disclose pharmaceutical compositions containing Tranilast and polyvinylpyrrolidone in the form of eye drops and nasal drop solutions (col. 2, lines 32-43). Yamamoto et al. fail to disclose barriers selected from the group consisting of film, foam, fibers, and filaments.

Accordingly, none of the cited references anticipates the present claims. Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al.

Claims 14, 27-30, 34 and 39 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest barriers selected from the group consisting of film, foam, fibers, and filaments containing Tranilast or analogs thereof.

The Examiner cites Mori et al. for the proposition that it would have been obvious to utilize the dosages set forth in the present claims in view of Mori et al.'s disclosure of dosages of 8-10 $\mu\text{g/g}$ for use in oral administration of Tranilast to treat keloid or allergic dermatitis.

While reserving comment on the distinctions between oral administration and the administration pathways disclosed in the present application, Applicants reiterate that Mori et al. fail to disclose or suggest barriers selected from the group consisting of film, foam, fibers, and filaments containing Tranilast, and as such, cannot meet all the limitations of the present claims. Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

Rejection under 35 U.S.C. 103(a) over Isaji et al. (Article)
in view of Akhtar et al.

Claims 14, 22, 23, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Isaji et al. ("Tranilast: A New Application in the Cardiovascular Field as An Antiproliferative Drug"), hereinafter referred to as the "Isaji Article", in view

Application No.: 10/797,367
Amendment Dated: July 8, 2008
Reply to Office Action Mailed: February 8, 2008

of Akhtar et al. (U.S. 5,432,163). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The Isaji Article discloses a new application for Tranilast which is to suppress restenosis after percutaneous transluminal coronary angioplasty (PTCA) (Introduction, p. 288). The Isaji Article discloses only oral administration of Tranilast (p. 291, last paragraph; p. 293, last paragraph). The Isaji Article fails to disclose or suggest a barrier containing Tranilast or its analogs, as presently claimed.

Akhtar et al. disclose anti-proliferative and anti-inflammatory compounds which are derivatives of pentose monosaccharides (title). The Akhtar et al. compounds are disclosed to administered orally, topically, rectally, anterally, internally, by boluses, or parenterally, preferably orally, in forms such as granules, powders, coated tablets, microcapsules, suppositories, syrups, elixirs, suspensions, emulsions, drops or injectable solutions (col. 8, lines 40-47). Akhtar et al. fail to disclose or suggest incorporating their new compounds in barriers selected from the group consisting of film, foam, fibers, and filaments and therefore cannot cure the deficiency of the Isaji Article.

Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al.
in view of Pope et al.

Claims 14, 22, 23, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. in view of Pope et al. (U.S. 5,948,822). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest barriers selected from the group consisting of film, foam, fibers, and filaments containing Tranilast or analogs thereof.

Pope et al. disclose topically administering a C18 to C26 aliphatic alcohol to a skin lesion in a pharmaceutically acceptable carrier (abstract) for treating or inhibiting the growth of hyperproliferative skin lesions, wherein the carrier may be white petrolatum, isopropyl myristate, lanolin or lanolin alcohols, mineral oil, sorbitan mono-oleate, propylene glycol, cetylstearyl alcohol, which can be combined with a detergent and mixed with water to form a lotion, gel, cream or semi-solid composition (col. 3, lines 41-49).

Pope et al. fail to cure the deficiency of Mori et al., since Pope et al. fail to disclose or suggest incorporation of their preparations in combination with Tranilast in a barrier selected from the group consisting of film, foam, fibers, and filaments, as claimed herein. Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

**Rejection under 35 U.S.C. 101 for provisional double patenting over
copending application no. 10/714,719**

Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected under 35 U.S.C. 103(a) for statutory double patenting over claims 14-41 of copending application no. 10/714,719.

Upon notification of allowable subject matter in the present application, Applicants agree to cancel claims 14-41 of the copending application.

Application No.: 10/797,367
Amendment Dated: July 8, 2008
Reply to Office Action Mailed: February 8, 2008

**Rejection for provisional nonstatutory double patenting over copending
application no. 10/780,452 in view of Chandrasekar et al.
Or Miyazawa et al.**

Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14-19, 21-24 and 27-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of Pemirolast and Tranilast on Intimal thickening after arterial injury in the rat").

Upon notification of allowable subject matter in the present application, Applicants will submit a terminal disclaimer over copending application no. 10/780,452.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14793).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

If the Examiner has any questions or wishes to discuss this application,

Application No.: 10/797,367
Amendment Dated: July 8, 2008
Reply to Office Action Mailed: February 8, 2008

the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Mlotkowski", written over a horizontal line.

Michael J. Mlotkowski
Reg. No. 33,020
Attorney for Applicants
703-584-3270

DATED: July 8, 2008

CORRESPONDENCE ADDRESS:

Roberts Mlotkowski Safran & Cole
P.O. Box 10064
McLean, VA 22102